K122892

510(k) Summary

per 21CFR807.92

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DEC 1 1 2012

DATE PREPARED: November 27, 2012

TRADE OR PROPRIETARY NAME: MTA2 ROOT AND PULP MATERIALS

CLASSIFICATION NAME: Root Canal Filling Resin 872.3820

PREDICATE DEVICES: K011009, White MTA Material and K080203, MTA root canal sealer

DEVICE DESCRIPTION: The MTA2 ROOT AND PULP MATERIALS are designed and developed for dentists to use in dental procedures that contact with vital pulp tissue and periradicular tissue, as well as obturation and sealing of root canals. The MTA2 ROOT AND PULP MATERIALS can be used for dental procedures such as: pulp capping, cavity lining, base material in a cavity, pulpotomies, root-end filling, apexification, perforation repair, root resorption, and sealing/obturation.

The dentist mixes the powder with the provided gel and places the mixed MTA2 material into the space created by the procedure. The procedure may be part of caries treatment, root canal treatment, or periapical surgery. The MTA2 ROOT AND PULP MATERIALS are available in white or gray.

INTENDED USE: The MTA2 ROOT AND PULP MATERIALS are intended for use in dental procedures that contact pulp and periradicular tissues, as well as obturation and sealing of root canals.

TECHNOLOGICAL CHARACTERISTICS: The MTA2 ROOT AND PULP MATERIALS are primarily hydraulic tricalcium silicate powders that are substantially similar to the powders in White MTA material (K011009) and MTA root canal sealer (K080203), which are also primarily tricalcium silicate cements. The tricalcium silicate-based materials are known to set with water into a hard substance, containing calcium hydroxide dispersed among the hydrated particles of tricalcium silicates. Both the MTA2 MATERIALS and the predicate devices are made radiopaque by adding Bi_2O_3 powder during manufacturing.

COMPARISONS TO PREDICATES: We believe the MTA2 ROOT AND PULP MATERIALS are substantially equivalent to the WHITE MTA MATERIAL (K011009), when used for contact with pulp tissue and periapical tissue, and substantially equivalent to MTA root canal sealer (K080203), when used as a root canal sealer.

Similarities: The predicates (White MTA Material & MTA root canal sealer) and the MTA2 ROOT AND PULP MATERIALS are based on an inorganic powder composed of primarily tricalcium silicate, dicalcium silicate, and bismuth oxide. The predicates and the MTA2 ROOT AND PULP MATERIALS rely on water to hydrate the calcium silicate phases, and cause setting into a hard substance containing hydrated silicates and some calcium hydroxide.

Both the MTA2 ROOT AND PULP MATERIALS and the predicate White MTA Material are used in root canals or on vital pulp tissue. Both the MTA2 ROOT AND PULP MATERIALS

and the predicate MTA root canal sealer are used for sealing and obturation of root canals. The predicate MTA root canal sealer and the MTA2 ROOT AND PULP MATERIALS are similar because both kits contain a gel.

The new and predicate materials had similar compositions, radiopacity, film thickness, flow and compressive strengths, when mixed at similar powder to liquid/gel ratios. Both MTA2 MATERIALS and the predicate materials induce the precipitation of hydroxyapatite crystals in synthetic body fluid.

Differences: Both a white version and a gray version of MTA2 ROOT AND PULP MATERIALS will be offered, whereas the White MTA predicate is whitish and the MTA root canal sealer is yellowish. However gray forms of MTA have also been considered substantially equivalent (such as K96174, K980332, and K981620).

The predicate White MTA Material and MTA root canal sealer differ from the MTA2 ROOT AND PULP MATERIALS differ because the MTA2 ROOT AND PULP MATERIALS contain a finer powder.

The predicates White MTA Material and the MTA2 ROOT AND PULP MATERIALS differ because the MTA2 ROOT AND PULP MATERIALS kits will contain a gel to create the consistency desired. The predicate White MTA kit contains only water; however, the predicate MTA root canal sealer (K080203) has a gel.

The predicate White MTA Material and the MTA2 ROOT AND PULP MATERIALS differ because the MTA2 ROOT AND PULP MATERIALS are suitable for use as a sealer, meeting the requirements of ADA 57. The predicates (White MTA Material and the MTA root canal sealer) differ from the gray form of MTA2 ROOT AND PULP MATERIALS differ because the gray form contains an additional component.

NON-CLINICAL PERFORMANCE: MTA2 ROOT AND PULP MATERIALS met the ADA 57 standard for radiopacity, solubility, dimensional stability, film thickness, and flow. The ADA 57 tests were also performed to measure the working time and setting time of MTA2 compared to the predicates. Tests for compressive strength and leaching of arsenic and lead were performed to shown conformance to ISO 9917. Analyses of the compositions were performed by x-ray diffraction and x-ray fluorescence. Washout, particle size analysis, and hydroxyapatite formation tests were also performed.

The MTA2 ROOT AND PULP MATERIALS were evaluated for biocompatibility with the gel in cytotoxicity and implantation tests.

CLINICAL PERFORMANCE: No clinical tests were performed in the development of the MTA2 ROOT AND PULP MATERIALS.

SUBSTANTIAL EQUIVALENCE: Bench testing was performed to ensure biocompatibility and that the requirements were achieved to conform to the FDA recognized standards ADA 57, ISO 6876, and appropriate requirements of ISO 9917.

We believe that the performance data provided herein demonstrate that MTA2 ROOT AND PULP MATERIALS are substantially equivalent to the predicates in design, principle of performance, technology, and composition. We believe the MTA2 ROOT AND PULP MATERIALS perform as well as or better than the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

December 11, 2012

Ms. Carolyn M. Primus
President
Avalon Biomed Incorporated
7282 55th Avenue E # 227
Bradenton, Florida 34203

Re: K122892
Trade/Device Name: MTA2 Root And Pulp Materials
Regulation Number: 21 CFR 872.3820
Regulation Name: Root Canal Filling Resin
Regulatory Class: II
Product Code: KIF
Dated: November 12, 2012
Received: November 19, 2012

Dear Ms. Primus:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations; Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kwame O. Ulmer

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
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Enclosure

Indications for Use

510(k) Number (if known): K122892

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Susan Runner DDS, MA 2012.12.11 15:00:24 -05'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: _____

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)
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